



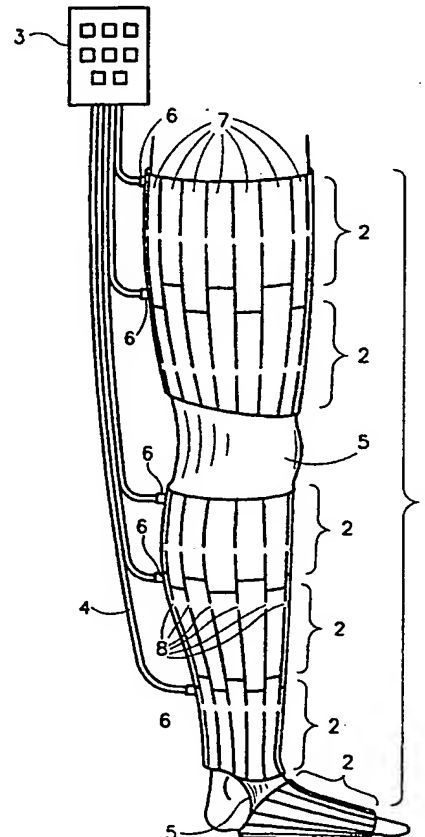
INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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(21) International Application Number: PCT/IL98/00378 (22) International Filing Date: 13 August 1998 (13.08.98) (30) Priority Data: 121661 31 August 1997 (31.08.97) IL 09/038,157 11 March 1998 (11.03.98) US (71) Applicant (for all designated States except US): MEDICAL COMPRESSION SYSTEMS (D.B.N.) [IL/IL]; Harugei Malhut Street 9, 69714 Tel Aviv (IL). (72) Inventor; and (75) Inventor/Applicant (for US only): BARAK, Jakob [IL/IL]; Haoren Street 20, 44813 Oranit (IL). (74) Agent: REINHOLD COHN AND PARTNERS; P.O. Box 4060, 61040 Tel Aviv (IL).		(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, GM, HR, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG). Published With international search report.	

(54) Title: DEVICE FOR PRESSURIZING LIMBS

(57) Abstract

A device for applying pressure to a body limb comprising a sleeve containing individually inflatable cells each cell being subdivided into longitudinally extending confluent compartments that are inflated and deflated essentially simultaneously. A device for applying pressure to a body comprising the massaging sleeve, means for the intermittent inflation selected cells of the sleeve; and means for determining a temporo-spatial regime of cell inflation. A method for immobilizing a fractured bone in a limb comprising inserting the limb into the sleeve and inflating all the cells in the sleeve. A method of massaging a limb of the body of an individual, comprising inserting the limb into the sleeve and inflating the cells of the sleeve according to a predetermined temporo-spatial regime.



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DEVICE FOR PRESSURIZING LIMBS

FIELD OF THE INVENTION

The present invention relates to medical devices and more specifically to devices for immobilizing or massaging body limbs, for example, in cases of edema, vein disorders such as chronic venous insufficiency (c.v.i.), varicose veins (v.v), varicose ulcers (v.u.) and others; 5 prevention of deep vein thrombosis; and bone fractures.

GLOSSARY

In the following description and claims the terms "*sleeve*" and 10 "*cell*" mean:

Sleeve - a hollow cylinder formed of a flexible material into the lumen of which a body limb, e.g. an arm, leg or foot, may be inserted.

15 *Cell* - A section of a massaging sleeve which may be inflated or deflated independently of the remainder of the sleeve.

BACKGROUND OF THE INVENTION

In the condition known as edema, interstitial fluid is 20 inadequately drained by the lymphatics. This causes an accumulation of fluid in the affected tissues leading to painful swelling. When this occurs in a body limb, beneficial results are obtained by massaging the limb in such a way as to force the fluid towards the proximal end of the limb and into the trunk of the

body. A number of apparatuses have been devised for this purpose, for example, as disclosed in U.S. Patent Nos. 5,117,812, 5,007,411, 5,025,781 and 5,591,200. In these apparatuses the limb to be treated is inserted into a massaging sleeve having a plurality of essentially circumferential cells along its length. Each cell is capable of being individually inflated by forcing a fluid into the interior of the cell in order to apply pressure to the limb segment contained within the cell. Each cell is made to undergo cycles of inflation and deflation in order to apply intermittent pressure on the limb segment which it encloses thus achieving a massaging effect on the limb. The inflation-deflation cycles of the different cells in the sleeve are typically staggered so as to generate peristaltic contractions of the sleeve, thus moving fluids inside the limb towards the trunk. In addition to being of benefit in cases of edema, these devices are also useful in the treatment of c.v.i., v.v., v.u. and the prevention of deep vein thrombosis.

In prior art devices, each cell in the sleeve, when deflated, forms essentially a circumferential band around the limb, the circumference of which is selected to correspond to the circumference of the limb segment contained within the cell. Upon inflation, the cell assumes essentially a toroidal shape. In this case, a decrease in the inner circumference of a cell upon inflation is accompanied by an essentially identical increase in the outer circumference of the cell. For example, in order to obtain a 36% decrease in the inner circumference of a cell upon inflation, the outer circumference of the inflated cell must be 36% larger than the original circumference of the limb segment contained therein. The fractional decrease in the inner circumference of the cell corresponds to the amount of pressure applied by the inflated cell to the limb segment contained therein. Thus, in order to obtain useful levels of pressure using prior art devices, the sleeve is of necessity very bulky, stiff and uncomfortable in use and relatively large and powerful compression pumps

are required. Prior art devices therefore require the individual to be immobilized during treatment for prolonged periods of time.

It is therefore the object of the present invention to provide a limb massaging device in which the aforementioned disadvantages of the prior art devices are substantially reduced or eliminated.

SUMMARY OF THE INVENTION

In accordance with a first aspect of the present invention there is provided a device for applying pressure to a body limb, comprising a sleeve containing a plurality of individually inflatable cells, each cell being subdivided into two or more longitudinally extending confluent compartments which are inflated and deflated essentially simultaneously.

The device according to the invention may, for example, be used to immobilize a fractured bone in a limb by inserting the limb into the sleeve and inflating all the cells thereof so as to render the sleeve rigid and inflexible for the duration of the treatment.

By one mode the invention provides a device for applying pressure to one or more limbs of the body comprising:

- (a) a sleeve containing a plurality of individually inflatable cells, each cell being subdivided into two or more longitudinally extending confluent compartments which are inflated and deflated essentially simultaneously;
- (b) means for the separate and intermittent inflation of any one of said plurality of inflatable cells; and
- (c) control means for determining the temporo-spatial regime of cell inflation.

Typically, and by way of a non-limiting example, a temporo-spatial regime of cell inflation is selected which generates peristaltic contractions of the sleeve. For example, with a sleeve containing 5 cells

numbered consecutively from the distal to the proximal end of the limb, cell 1 would first be inflated, followed by cell 2. Cell 1 would then be deflated and cell 3 inflated. Next, cell 2 is deflated as cell 4 is inflated, and then cell 3 is deflated and cell 5 inflated. Finally, cell 4 and then cell 5 are deflated and the cycle begins again. Other temporo-spatial regimes of cell inflation are also contemplated within the scope of the invention.

In accordance with a third aspect of the present invention there is provided a method of massaging a limb of the body of an individual comprising: inserting the limb to be treated into a massaging sleeve of the kind specified and inflating the cells of the sleeve according to a predetermined temporo-spatial regime.

The device according to the invention is applied for example, in cases of edema, c.v.i., v.v., v.u. or preventing deep vein thrombosis.

As will become evident through the description below, subdividing the cells of the sleeve into compartments according to the present invention yields several advantages over prior art devices. Since the diameter of the inflated sleeve is not substantially larger than the diameter of the treated limb, the sleeve may be worn under clothing and is thus concealed during use. Moreover, the sleeve remains flexible and comfortable during use so that the individual need not be immobilized during treatment. Furthermore, the volume of the inflated cells in the present invention is substantially less than in prior art devices, so that a much smaller compressor need be used for inflating the cells. This in turn allows the controlling unit to be substantially lighter than is required for prior art devices. These features allow the individual to be completely ambulatory during treatment.

While in the description given below, the cells in the sleeve are aligned to form an elastic cylinder, the invention is not bound by this constraint and other types of sleeves are contemplated within the scope of the invention. For example, the sleeve may initially be a pad which is wrapped

around the limb into an essentially cylindrical shape and then fastened in this configuration by various means.

In operation, a cell is inflated by forcing a fluid into the interior of the cell between the inner and outer shells. While in the description given below a deflated cell forms an essentially circumferential band around the limb, and the fluid used to inflate the cell is air, the invention is not bound by these constraints, and other cell shapes and fluids are contemplated within the scope of the invention.

10 BRIEF DESCRIPTION OF THE DRAWINGS

The invention will now be demonstrated by way of a non-limiting example, with reference to the accompanying drawings in which:

Fig. 1 shows a massage sleeve according to the invention in use on the leg of an individual;

15 Fig. 2 shows a massage sleeve according to the invention mounted on the leg of an individual drawn to a larger scale;

Fig. 3 shows a fractional perspective view of a massage sleeve according to the invention fitted with a control unit; and

20 Fig. 4a and 4b show a cross-section of a cell in the deflated and inflated states, respectively.

DESCRIPTION OF A SPECIFIC EMBODIMENT

In the following, an embodiment of the invention will be described for use on the leg of an individual. However, it is to be understood that the invention is also intended for use on any body limb such as an arm, a foot, a part of a leg, arm or foot, and may be used on two or more limbs simultaneously.

In Fig. 1, a patient is depicted wearing a massaging sleeve 1 of the invention on her leg while carrying out her routine duties. In Fig. 1, the

trouser leg of the patient is cut away to reveal the sleeve. In practice, however, the sleeve remains concealed from view, and due to the facets of the present invention remains unnoticed even during operation when the cells are intermittently inflated. The sleeve 1 has an inner and outer surface composed of a durable flexible material and is divided into a plurality of cells 2 along its length and each cell is connected to the control unit 3 by a separate tube collectively labeled 4 in Fig. 1. Sections of the sleeve may be of non-inflatable elastic material, for example around the knee and ankle 5.

As can be seen in Figs. 2 and 3, each cell has a fluid inlet opening 6 to which a hose 4 from the control unit 3 is attached. The control unit 3 contains a compressor capable of compressing and pumping ambient air into one or more selected cells in the sleeve via the hoses 4. The control unit 3 allows a temporo-spatial regime of inflation and deflation of the cells to be selected, e.g. a regime which generates peristaltic contractions of the sleeve so as to force fluids inside the limb towards the proximal end of the limb, or a regime which enhances the flow of the venous blood in the limb. The continuity of the peristalsis is enhanced by interdigitating the compartments of adjacent cells in the massaging sleeve as shown in Figs. 2 and 3.

In accordance with the present invention, the cells are subdivided into a plurality of longitudinally extending compartments 7. The compartments are formed, for example, by welding the inner and outer shells of the massaging sleeve along the boundaries of the compartments. The compartments in a given cell are confluent due to perforations 8 in the seams between adjacent compartments so that all the compartments in the cell are inflated or deflated essentially simultaneously. Each compartment, when inflated, assumes essentially the shape of a cylinder having its axis parallel to that of the limb.

A cross-section of a deflated cell is shown in Fig. 4a, and Fig. 4b shows the same cross-section after inflation. The cell has been

divided, by way of example, into ten identical compartments, it being self-evident that any other number of compartments may be used. If N is the number of compartments in a given cell, and r is the radius of an inflated compartment, then as can be seen in Fig. 4b the length of the circumference
 5 10 that passes through the centers of the inflated compartments will be $2Nr$, whereas the circumference $9'$ of the deflated cell is . The fractional decrease in the circumference upon inflation is thus

$$\frac{N\pi r - 2Nr}{\pi Nr} = 1 - \frac{2}{\pi} = 0.36. \quad (1)$$

10 The length of the inner circumference $9'$ of the inflated cell will be less than $2Nr$ so that the fractional decrease in the inner circumference upon inflation is thus grater than 0.36.

N and r are chosen so that

deflated cell) corresponds to the original circumference of the limb segment
 15 contained within the lumen of the cell. The fractional decrease in the circumference of the cell upon inflation (0.36) causes a contraction of the cell whereby pressure is applied to the limb which, as follows from equation (1) above, is independent of N and r. Thus, by choosing N sufficiently large, and r correspondingly small, a sleeve is obtained having an inflated outer
 20 circumference not substantially larger than the original circumference of the limb. This is in contrast to prior art devices which, as shown above, must have an outer circumference 36% greater than the initial circumference of the limb in order to achieve the same applied pressure as that produced by the present invention.

25 Letting now L be the length of a cell and $C = N\pi r$, the initial circumference of the limb contained within the cell, it is readily appreciated from Fig. 4 that the initial volume of the limb contained within the deflated

cell is $V_D = \pi \left(\frac{C}{2\pi} \right)^2 L$. The final volume of the limb contained within the inflated cell is less than $V_I = \pi \left(\frac{0.64C}{2\pi} \right)^2 L = 0.41V_D$. Inflating the cells thus leads to a decrease in the volume of the limb contained within the cell of about 59%. This represents the volume of fluid squeezed out of the limb, or the work performed by the sleeve. This is accomplished by inflating the compartments of the cell to a total volume of $V_T = N\pi r^2 L = N\pi \left(\frac{C}{N\pi} \right)^2 L = \frac{C^2 L}{N\pi}$. In contrast to this, obtaining the same decrease in the volume of the limb by prior art methods requires inflating a cell to a final volume of $V_F = \pi \left\{ \left(\frac{1.36C}{2\pi} \right)^2 - \left(\frac{0.64C}{2\pi} \right)^2 \right\} L = \frac{C^2 L}{2.8\pi}$. Thus, when the number of compartments in the cell of the present invention is at least 3, the volume to which the cell must be inflated is less than that of prior art devices. Moreover, by choosing N sufficiently large, a decrease of 59% in the volume of the limb can be obtained by inflating the cell to an arbitrarily small total volume. For example, when $N = 30$, the total volume of the inflated cell is less than one-tenth of the volume of the inflated cell of the prior art devices. This allows a much smaller compressor to be used than is possible with prior art sleeves, thus permitting the patient to be ambulatory while being treated by the invention.

It is noted that a sleeve according to the invention, e.g. such as sleeve 1 in Figs. 1 and 2 or a smaller sleeve covering only a portion of a limb, may be used for immobilization of a fractured bone in a limb.

It is noted that the compartments of a given cell may be of different diameters.

If desired, it is noted that the sleeve of the invention may be incorporated into a slipper to be worn on a person's foot. For example, a

slipper may be designed comprising a sleeve of the specified type formed so as to receive a person's foot, and a rigid sole attached to the sleeve.

Furthermore, the sleeve of the invention may optionally be heated or cooled to a desired temperature by methods known in the art, so as to achieve a desired effect on the patient. For example, the fluid used to inflate the cells of the sleeve may be heated or cooled to a desired temperature prior to inflation.

Also if desired, the sleeve of the invention may be incorporated into a knee protector to be worn on a person's knee. For example, a knee protector may be designed comprising a sleeve of the specified type formed so as to receive a person's knee, and a rigid shield to be placed over the knee and attached to the sleeve.

By yet another option, the sleeve of the invention may be used under a rigid cast to be applied to a person's limb, for example, when immobilizing a fractured bone. Use of the sleeve under a cast is desirable, for example, to treat edema accompanying prolonged wearing of a cast or to prevent deep vein thrombosis.

The invention may, if desired, be used in a pressure suit, for example, to achieve external counterpulsation of the blood flow in a patient or in cases of trauma. For example, one or more sleeves of the invention may be incorporated in a pair of trousers and the cells of the sleeves are, for example, inflated when the patient's heart is in diastole, and deflated when the heart is in systole; alternatively, the cells of all sleeves are inflated simultaneously so as to stop hemorrhaging in the lower part of the body.

It is also noted that the sleeve may optionally contain an inner lining to prevent the patient's skin from being pinched and to enhance the equalization of pressure distribution to the skin as the compartments are inflated. The inner lining may be made out of different materials such as, for example, silicon.

CLAIMS:

1. A device for applying pressure to a body limb comprising a sleeve containing one or more individually inflatable cells each cell being
5 subdivided into two or more longitudinally extending confluent compartments which are inflated and deflated essentially simultaneously.
2. A device for applying pressure to a body limb comprising:
 - (a) a sleeve containing one or more individually inflatable cells each cell being subdivided into two or more longitudinally extending
10 confluent compartments which are inflated and deflated essentially simultaneously;
 - (b) means for the intermittent inflation of any one or more selected cells of the sleeve; and
 - (c) means of determining the temporo-spatial regime of cell
15 inflation.
3. The device of Claim 2, in which the cells are inflated by means of compressed air.
4. The device of Claim 1 or 2, in which the compartments of adjacent cells of the massaging sleeve are interdigitated.
- 20 5. The device of any one of Claims 1 to 4, serving for the treatment of any one of the disorders selected from the group of edema, chronic venous insufficiency, varicose veins and varicose ulcers.
6. The device of any one of Claims 1 to 4, serving for the prevention of deep vein thrombosis.
- 25 7. The device of any one of Claims 1-4, serving for immobilizing a fractured bone.
8. A method for immobilizing a fractured bone in a limb comprising inserting the limb into a massaging sleeve of the kind specified, and inflating all the cells in the sleeve.

9. A method of massaging a limb of the body of an individual, comprising inserting the limb to be treated into a massaging sleeve of the kind specified and inflating the cells of the sleeve according to a predetermined temporo-spatial regime.
- 5 10. A slipper comprising the device of any one of Claims 1 to 4.
11. A knee protector comprising the device of any one of Claims 1 to 4.
12. A pressure suit comprising the device of any one of Claims 1 to 4.
- 10 13. A device of any one of Claims 2 to 7, further comprising means for controlling the temperature of the sleeve.
14. The device of Claim 1 or 2, further comprising an inner lining.

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FIG. 1

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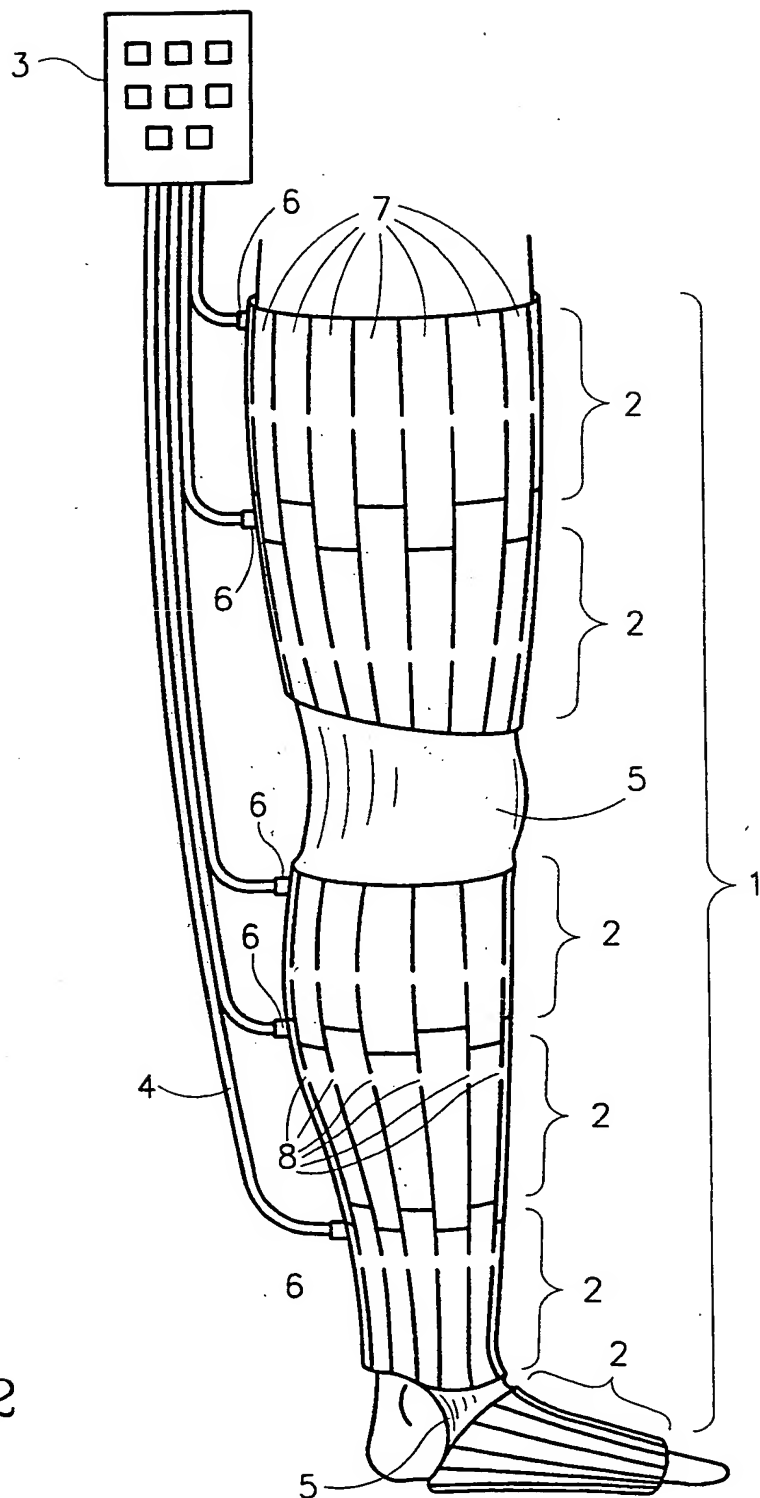


FIG.2

3/4

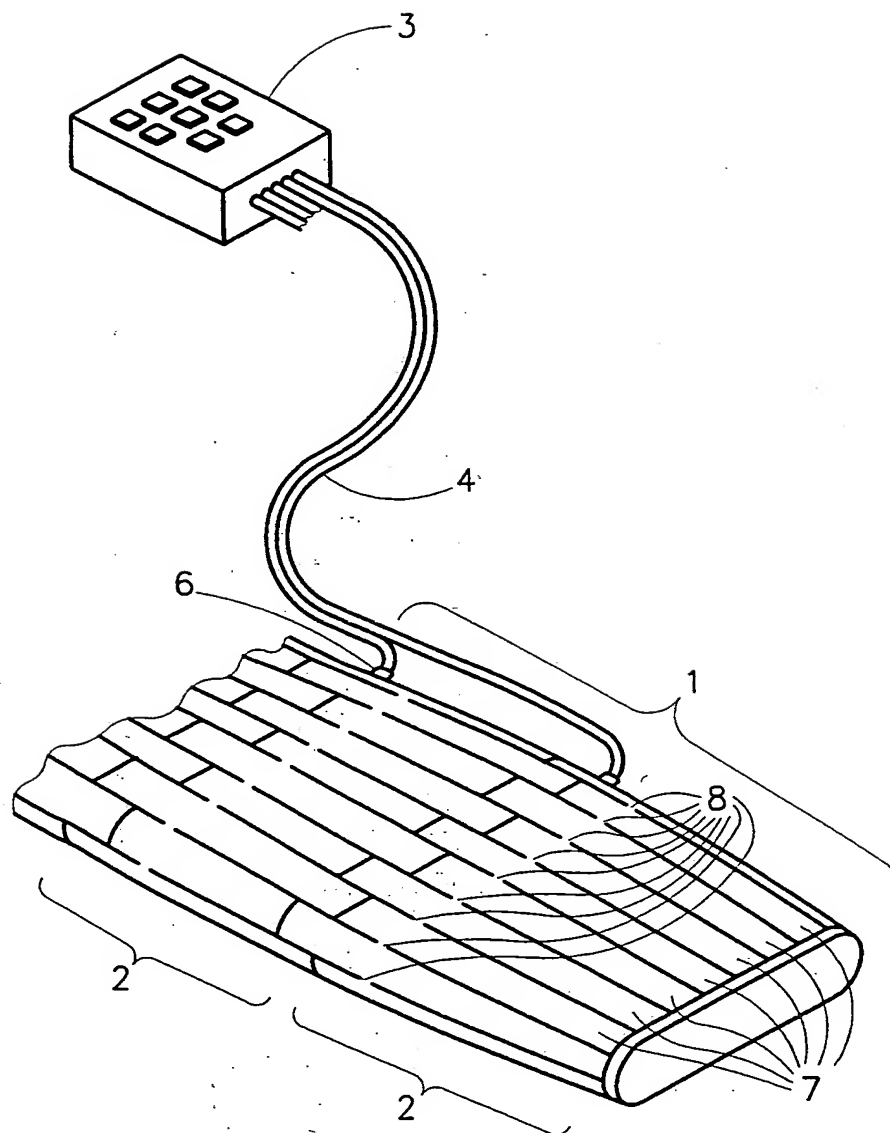


FIG.3

4/4

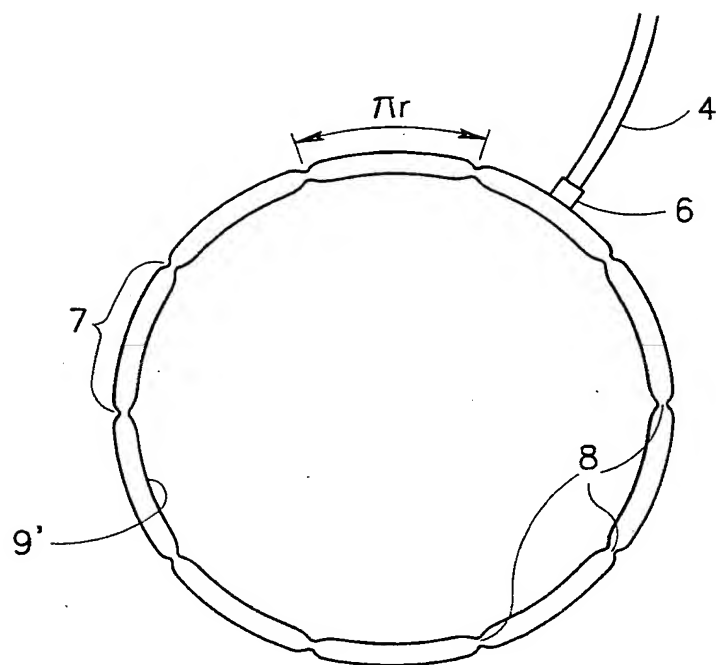


FIG. 4A

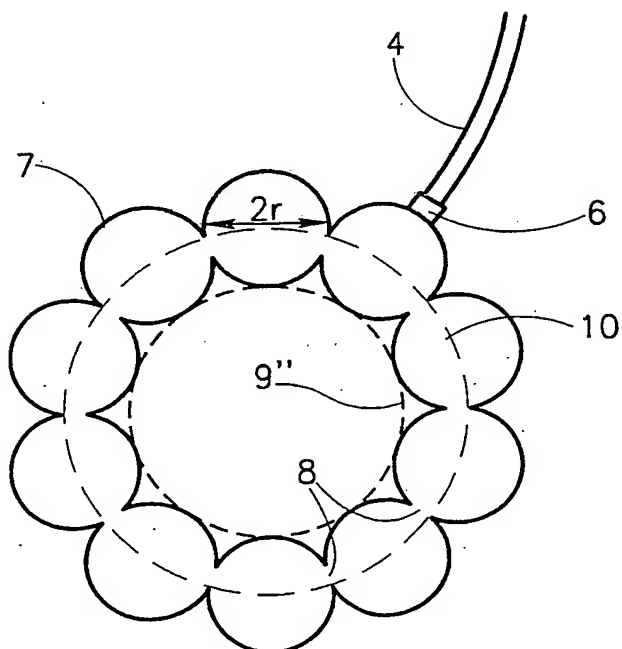


FIG. 4B

INTERNATIONAL SEARCH REPORT

In ternational Application No

PCT/IL 98/00378

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61H23/04

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61H A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	DE 19 03 217 A (CONTI) 16 April 1970 see claims 3,9,11; figures ---	1-3,5, 11-13
X	EP 0 388 200 A (THE KENDALL COMPANY) 19 September 1990	1-3,5,6, 12
Y	see column 9, line 1 - line 6; figures 1-5 see column 13, line 24 - line 37 ---	7,14
Y	US 5 288 286 A (DAVIS ET AL.) 22 February 1994 see abstract; figures 1-5 ---	7
X	DE 27 10 677 A (SWOBODA) 14 September 1978 see page 2, line 22 - line 50; figures ---	1-3
X	US 2 880 721 A (CORCORAN) 7 April 1959 see figures 1-5 ---	1,10
	-/--	

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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Date of the actual completion of the international search

10 December 1998

Date of mailing of the international search report

18/12/1998

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Jones, T

INTERNATIONAL SEARCH REPORT

International Application No

PCT/IL 98/00378

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 4 573 453 A (TISSOT) 4 March 1986 see column 2, line 62 - line 68; figures ----	14
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INTERNATIONAL SEARCH REPORT

International application No.

PCT/IL 98/00378

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 8, 9
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/IL 98/00378

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